

R E M A R K S

The Official Action of November 16, 1978 has been carefully considered. By this amendment, the specification is being amended to indicate the current status of Applicants parent application USSN 838,603 and to include material which describes the microorganism which prepares the C-076 starting materials, and also material describing the isolation of the C-076 starting materials from the fermentation broth. Also claims 15 and 16 have been cancelled. The claims remaining in the case are 1-14 and 17-22.

Claims 1-22 stand rejected under the first and second paragraphs of 35 USC 112. The Examiner indicated that there was insufficient disclosure directed to the preparation of the C-076 starting materials. By this amendment, the instant specification is being amended to include material which describes the preparation of the C-076 starting materials. This material is taken from USSN 772,601 which is disclosed in the instant specification on page 1 line 9. Also enclosed herewith is an Affidavit, signed by Applicants Attorney, indicating that the material now being added by amendment is the same as that found in the referenced application. Thus the rejection under the first and second paragraphs of 35 USC 112 is completely avoided, since the instant application now contains the disclosure required by the Examiner.

Claims 1-14 and 17-22 stand rejected under 35 USC 103 as being obvious in view of the application disclosing the C-076 starting materials. The structure of the C-076 starting materials is set out on page 2 on line 2 et seq. The structure of the instant compounds is set forth on page 3, line 21 et seq. and as noted on page 3 lines 12-15, the difference between the instant compounds and the starting materials consists of the saturation of the 22,23 double bond which is found only in the A1 and B1 series of compounds. The Examiner states that the instant compounds are thus prima facie obvious over the C-076 starting materials. Applicants Attorney respectfully disagrees.

An analysis of the instant case and the prior art case will reveal that there are five double bonds in the C-076 starting materials. The instant specification describes the reduction of just one specific double bond, leaving the other intact. There is no teaching in the reference disclosing the C-076 compounds or in any of the other references, which would suggest to one skilled in the art how to selectively reduce only the 22,23 double bond of the C-076 compounds. The C-076 reference discloses the preparation of the C-076 compounds from a microbiological fermentation. There is nothing which suggests that any of the double bonds and certainly not the specific 22,23 double bond, should be reduced. The other references, which show the reduction of other macrolides, and reducing

agents, disclose nothing which would indicate that the specific double bond in question should be reduced.

It is respectfully submitted that one skilled in this art would find nothing in the prior art which would suggest the instant compounds and any process which would lead to the preparation of such compounds, and not other reduced compounds. The rejection should be withdrawn.

While Applicants Attorney submits that there is inadequate basis in the prior art for a rejection under 35 USC 103, in order that there can be no question as to this matter, material is being assembled which will demonstrate the superior and unexpected properties of the instant compounds over the prior art compounds. Unfortunately, the Affidavit is not ready at this time, due to the time required to bring together all of the relevant data, and the fact that there is considerable data which is being examined. The Affidavit should be ready soon, however, and when it is completed, it will be promptly forwarded to the Examiner.

Claims 15 and 16 stand rejected under 35 USC 103 as being obvious over references A and R. Claims 15 and 16 have been cancelled, thus avoiding the rejection and rendering further discussion unnecessary.

Claims 1-22 stand rejected under 35 USC 101 and 103 for obvious double patenting over the claims of copending application USSN 838,603. The application referred

to is the parent application to the instant application as indicated on page 1 lines 5-7. The rejection has been avoided since said application is now abandoned. The claims in said application are being prosecuted herein. The Cross Reference to Related applications has been amended to include the current status of parent application USSN 838,603. The rejection is thus avoided and the Examiner is requested to reconsider and withdraw the rejection.

Applicants Attorney notes the Examiner's acknowledgement of the references and Discussion of Prior Art submitted by Applicants Attorney. Applicants Attorney submits that the instant claims are patentable over said prior art.

All of the rejections and objections of the Official Action of November 16, 1978 have been avoided and that the instant claims are in condition for allowance. A prompt Notice of Allowance is respectfully solicited.

Respectfully submitted,

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Enclosure

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 20231, on the date appearing below.

MERCK & CO., INC.  
By David L. Rose Date 2/13/79  
David L. Rose